

Form PTO-1449

INFORMATION DISCLOSURE CITATION  
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AUG 31 2001

ocket Number (Optional)  
AKT-053.02Application Number  
09/787,325Applicant  
Stuart A. Fine et al.Filing Date  
September 17, 1999Group Art Unit  
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AN	RE 33,988	07/07/92	Evans	614	188	02/26/90
AB	4,921,877	05/01/90	Cashmere et al.	514	866	12/16/90
AC	4,959,222	09/25/90	Nadland et al.	424	692	09/23/88
AD	5,013,752	05/07/91	Dobbins	514	505	04/16/90
AE	5,045,316	09/03/91	Kaplan	424	400	12/21/87
AF	5,069,913	12/03/91	Posner et al.	424	646	09/12/89
AG	5,087,623	02/11/92	Boynton et al.	514	188	03/21/89
AH	5,087,624	02/11/92	Boynton et al.	514	188	07/13/90
AI	5,164,384	11/17/92	Paul	514	188	06/19/91
AJ	5,215,750	06/01/93	Keane II	424	440	09/04/91
AK	5,266,560	11/30/93	Furman et al.	514	4	09/09/91

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	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
AL	DE 298 05 782	09/10/98	Germany				X
AM	EP 0 834 318 A1	04/08/98	Europe				X
AN	EP 561 744 A1	09/22/93	Europe				X
AO	WO 91/11117	08/08/91	PCT				X
AP	WO 96/25939	08/29/96	PCT				X

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AK	"Chromium picolinate for good health?," Biolifeplus.com, 'Online! 10/16/99, XP002135607, <a href="http://www.biolifeplus.com/library/chromium.html">www.biolifeplus.com/library/chromium.html</a> , retrieved on 4/5/00
AR	Abbott et al., "The Impact of Diabetes on Survival Following Myocardial Infarction in Men vs Women," JAMA, 260(23):3456-3460 (1988)
AS	ACC/AHA Task Force Report, "Guidelines for the Early Management of Patients with Acute Myocardial Infarction; a Report of the American College of Cardiology/ American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee to Develop Guidelines for the Early Management of Patients with Acute Myocardial Infarction)," JACC, 16(2):249-292 (1990)

EXAMINER	DATE CONSIDERED
<i>J. C. Guan</i>	5/30/03

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BA	5,300,496	04/05/94	McNeill et al.	514	184	09/30/91
BB	5,308,627	05/03/94	Umbdenstock, Jr.	424	639	11/19/92
BC	5,332,579	07/26/94	Umbdenstock	424	639	11/20/92
BD	5,496,827	03/05/96	Patrick	514	310	07/15/94
BE	5,527,790	06/18/96	McNeill et al.	514	186	03/18/94
BF	5,532,269	07/02/96	Koltringer	514	440	10/11/94
BG	5,543,405	08/06/96	Keown	514	188	10/20/94
BH	5,550,113	08/27/96	Mann	514	54	07/20/94
BI	5,597,585	01/29/97	Williams et al.	424	579	12/26/95
BJ	5,599,835	02/04/97	Fisher	514	440	11/23/94
BK	5,614,224	03/25/97	Womack	424	646	04/20/95

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						YES	NO
BL	WO 96/35421	11/14/96	PCT				X
BM	WO 96/39871	12/19/96	PCT				X
BN	WO 97/11614	04/03/97	PCT				X
BO	WO 98/04248	02/05/98	PCT				X
BP	WO 98/41113	09/24/98	PCT				X

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BQ	Aharon et al., "Vanadul Sulfate Does Not Enhance Insulin Action in Patients with Type I Diabetes," Diabetes Care, 21:2194-2195 (1998)
BR	American Diabetes Association: "Nutrition Recommendations and Principles for People with Diabetes Mellitus," Diabetes Care, 19(1):S16-S19 (1996)
BS	American Diabetes Association: "Nutrition Recommendations and Principles for People with Diabetes Mellitus," Diabetes Care, 20(1):S14-S17 (1997)

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
PA	CA 5,620,967	04/15/97	McNeill et al.	514	186	06/07/95
	CB 5,635,535	06/03/97	Wagstaff	514	557	04/05/96
	CC 5,637,324	06/10/97	Bland	424	655	06/06/95
	CD 5,641,531	06/24/97	Liebrecht et al.	426	583	09/28/95
	CE 5,654,011	08/05/97	Jackson et al.	424	635	07/30/96
	CF 5,665,385	09/09/97	Johnson et al.	424	451	12/09/94
	CG 5,707,980	01/13/98	Knutson et al.	514	167	02/11/97
	CH 5,730,988	03/24/98	Womack	424	195.1	03/24/97
	CI 5,763,484	06/09/98	Horrobin	514	560	03/24/97
	CJ 5,770,215	06/23/98	Moshyedi	424	440	01/06/97
	CK 5,789,401	08/04/98	McCarty	514	188	08/08/97

**FOREIGN PATENT DOCUMENTS**

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						YES	NO
PA	CL WO 98/42211	10/01/98	PCT				X
	CM WO 99/07387	02/18/99	PCT				X
	CN WO 00/12095	03/09/00	PCT				X
	CO						
	CP						

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PA	CQ	Amoikon, et al., "Effect of chromium tripicolinate on growth, glucose tolerance, insulin sensitivity, plasma metabolites, and growth hormone in pigs," J. Anim. Sci. (1995) 73(4) 1123-30 XP000901969 Abstract
	CR	Anderson and Kozlovsky, "Chromium Intake, Absorption and Excretion of Subjects Consuming Self-Selected Diets," The American Journal of Clinical Nutrition, 41:1177-1183 (1985)
	CS	Anderson et al., "Elevated Intakes of Supplemental Chromium Improve Glucose and Insulin Variables in Individuals With Type 2 Diabetes", Diabetes 46:1786-1791 (1997).

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AUG 31 2001 JC41 PATENT & TRADEMARK OFFICE			Applicant Stuart A. Fine et al.	Group Art Unit 1617
			Filing Date September 17, 1999	

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JK	DA 5,807,586	09/15/98	Jackson et al.	424	630	07/30/96
	DB 5,817,329	10/06/98	Gardiner	424	439	02/28/97
	DC 5,849,338	12/15/98	Richardson et al.	424	682	03/18/97
	DD 5,866,563	02/02/99	McNeill et al.	514	186	06/07/95
	DE 5,871,769	02/16/99	Fleming et al.	424	423	04/23/97
	DF 5,905,075	05/18/99	Harpe et al.	514	188	08/28/98
	DG 5,908,647	06/01/99	Golightly et al.	426	74	04/11/97
	DH 5,962,030	10/99	Fine	424	646	11/05/97
JK	DT 5,980,905	11/09/99	De La Harpe et al.	424	195.1	04/14/99
	DJ					
	DK					

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						YES	NO
	DL						
	DM						
	DN						
	DO						
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JK	DQ	Anderson et al., "Urinary Chromium Excretion and Insulinogenic Properties of Carbohydrates,: Am J Clin Nutr, 51:864-868 (1990)
	DR	Anderson, Richard "Chromium, Glucose Intolerance and Diabetes," The American Journal of Clinical Nutrition, Vol. 17, No. 6 548-555 (1998)
	DS	Antiplatelet Trialists' Collaboration, "Collaborative overview of randomized trials of antiplatelet therapy-I: Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients," BMJ 308:81-106 (1994)

EXAMINER	<i>TJ Carty</i>	DATE CONSIDERED
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	EA	Arsenian, M.A., "Magnesium and Cardiovascular Disease," Progress in Cardiovascular Disease 35(4):271-310 (1993)
	EB	Arsenian, M.A., "Magnesium and the Autonomic Nervous System," Magnesium and Cardiovascular Disease 291-310 (1993)
	EC	Avins, "Lowering Risk without Lowering Cholesterol: Implications of National Cholesterol Policy" Annals of Internal Medicine 125 (6):502-506 (1996)
	ED	Bahadori et al., "Effects of Chromium Picolinate on Insulin Levels and Glucose Control in Obese Patients with Type-II Diabetes Mellitus" 140 Cite
	EF	Bailey, C.J., "Biguanides and NIDDM" Diabetes Care 15 (6):755-772 (1992)
	EG	Barnard, et al., "Diet and Exercise in Treatment of NIDDM; The need for early emphasis" Diabetes Care 17 (12):1469-1472 (1994)
	EH	Bayraktar, M., "A Comparison of Acarbose Versus Metformin as an Adjuvant Therapy in Sulfonylurea-Treated NIDDM Patients" Diabetes Care 19 (3):252-254 (1996)
	EI	Bierman, E.L., "Atherogenesis in diabetes" Arteriosclerosis and Thrombosis 12 (6):647-656 (1992)
	EJ	Bloomgarden, A.T., "American Diabetes Association Scientific Sessions, 1995; Magnesium Deficiency, Atherosclerosis, and Health Care" Diabetes Care 18 (12):1623-1627 (1995)
	EK	Boyd et al., "Combined dietary chromium picolinate supplementation and an exercise program leads to a reduction of serum cholesterol and insulin in college-aged subjects," J. Nutr. Biochem. (1998) 9(8), 471-475 XP000901922 Abstract
	EL	Caballero, "Vitamin E Improves the Action of Insulin" Nutrition Reviews 51 (11):339-340 (1993)
	EP	Calle-Pascual, A.L., "Comparison Between Acarbose, Metformin, and Insulin Treatment in Type 2 Diabetic Patients with Secondary Failure to Sulfonylurea Treatment" Diabète & Métabolisme (Paris) 21:256-260 (1995)
	EQ	Cam et al., "Long- term effectiveness of oral vanadyl sulphate in streptozotocin-diabetic rats", Diabetologia 36: 218-224 (1993)
	ER	Cefalu, et al, "Effect of Chromium Picolinate on Insulin Sensitivity In Vivo", The Journal of Trace Elements in Experimental Medicine 12:71-83 (1999)
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✓	ES	Cerulli et al., "Chromium Picolinate Toxicity", The Annals of Pharmacotherapy 32:428-431, ( April 1998).	
✓	ET	Cheng, et al, "Follow-up Survey of People in China with Type 2 Diabetes Mellitus Consuming Supplemental Chromium," The Journal of Trace Elements in Experimental Medicine 12:55-60 (1999)	
✓	EU	Chowdhury and Lasker, "Elevated glycated haemoglobin in non-diabetic patients is associated with an increased mortality in myocardial infarction", Postgrad. Med. J. 74: 480-481 (1998).	
✓	EV	ChromeMate: Research Summary.	140 Date etc
✓	EW	Clarke, R. J., "Suppression of Thromboxane A <sub>2</sub> but not of Systemic Prostacyclin by Controlled-Release Aspirin" The New England Journal of Medicine 325 (16):1137-1141 (1991)	
✓	EX	Classen, H. G., "Magnesium and Potassium Deprivation and Supplementation in Animals and Man: Aspects in View of Intestinal Absorption" Magnesium 3:257-264 (1984)	
✓	EY	Cohen and Kitzes, "Magnesium Sulfate and Digitalis-Toxic Arrhythmias" JAMA 249 (20):2808-2810 (1983)	
✓	EZ	Cohen, et al., Oral Vanadyl Sulfate Improves Hepatic and Peripheral Insulin Sensitivity in Patients with Non-Insulin-dependent Diabetes Mellitus" J. Clin. Invest. 95:2501-2509 (1995)	
✓	FA	Colwell et al., "Correlation of Platelet Aggregation, Plasma Factor Activity, and Megathrombocytes in Diabetic Subjects With and Without Vascular Disease" Metabolism 26 (3):279-285 (1977)	
✓	FB	Dai et al., "One-year Treatment of Streptozotocin-Induced Diabetic Rats with Vanadyl Sulphate" Pharmacology & Toxicology 74:101-109 (1994)	
✓	FC	Davi et al., "Thromboxane B <sub>2</sub> Formation and Platelet Sensitivity to Prostacyclin in Insulin-Dependent and Insulin-Independent Diabetics" Thrombosis Research 26:359-370 (1982)	
✓	FD	Davi et al., "Thromboxane Biosynthesis and Platelet Function in Type 11 Diabetes Mellitus" The New England Journal of Medicine 322 (25):1769-1774 (1990)	
✓	FE	Davies et al., "Intramocardial Platelet Aggregation in Patients with unstable Angina Suffering Sudden Ischemic Cardiac Death " Circulation 73(3):418-427 (1986)	
✓	FF	Davis et al., "Monotherapy with Magnesium Increases Abnormally Low High Density Lipoprotein Cholesterol: A Clinical Assay" Current Therapeutic Research 36 (2):341-346 (1984)	
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<i>Re</i>	FG	De Tata, et al., "Beneficial Effects of the Oral Administration of Vanadyl Sulphate on Glucose Metabolism in Senescent Rats", Journal of Gerontology 48(5):B191- B195 (1993)
	FH	Defronzo et al., "Insulin Resistance; A Multifaceted Syndrome Responsible for NIDDM, Obesity, Hypertension, Dyslipidemia, and Atherosclerotic Cardiovascular Disease" Diabetes Care 14 (3):173-194 (1991)
	FI	DeFrone, R.A., "Efficacy Of Metformin in Patients with Non-Insulin-Dependent Diabetes Mellitus" The New England Journal of Medicine 33 (9):541-549 (1995)
	FJ	Dehghani et al., "Effect of Vanadyl Sulphate on Glucose Homeostasis in Severe Diabetes Induced by Streptozotocin in Rats", Indian J. Med Res. 106: 481-585 (1997).
	FK	Diabetes Pro Health " Akesis Pharmaceuticals Inc". (Pamphlet) Product first used no earlier than June of 1997
	FL	Diabetes Pro Health Inc. " Pro Health Pak" ( labels) Product described in label first sold no earlier than June of 1997
	FM	Diabetes Pro Health Inc. " Pro Health Pak" ( labels) Product described in label first sold no earlier than March of 1998.
<i>↓</i>	FN	Diabetes Pro Health Inc. " Pro Health Pak" ( labels) Product described in label first sold no earlier than October of 1999.
<i>TK</i>	FO	Diabetes Pro Health Inc., " Introducing A Nutritional Supplement Specifically Formulated For Adults With Diabetes & Pre- Diabetes" <i>No Date</i>
<i>TK</i>	FP	Dieber-Rotheneder et al., "Effect of Oral Supplementation with D- $\alpha$ -tocopherol on the vitamin E content of human low density lipoproteins and resistance to oxidation", Journal of Lipid Research 32: 1325- 1332 (1991).
	FQ	Domingo et al., "Administration of Vanadyl Sulfate by Gavage does not Normalize Blood Glucose Lvels in Streptozotocin-induced Diabetic Rats", Research Communications in Chemical Pathology and Pharmacology 75 (3) : 369- 372 (March 1992).
	FR	Domingo et al., "Tiron administration minimizes the toxicity of vanadate but not its insulin mimetic properties in diabetic rats," Life Sciences (1992) 50/18 (1311-1317), XP000901833
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	FT	Dubyak and Kleinzeller, "The Insulin-mimetic Effects of Vanadate in Isolated Rat Adipocytes" The Journal of Biological Chemistry 255 (11):5306-5312 (1980)
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	FU	ETDRS Investigators, "Aspirin Effects on Mortality and Morbidity in Patients With Diabetes Mellitus" <i>JAMA</i> 268 (10):1292-1300 (1992)	
	FV	Evans and Bowman, "Chromium Picolinate Increases Membrane Fluidity and Rate of Insulin Internalization", <i>Journal of Inorganic Biochemistry</i> 46: 243- 250 (1992).	
	FW	Evans and Pouchnik, " Composition and Biological Activity of Chromium -Pyridine Carboxylate Complexes", <i>Journal of Inorganic Biochemistry</i> 49 :177-187 (1993).	
	FX	Evans W. G., "The Effect of Chromium Picolinate on Insulin Controlled Parameters in Humans," <i>Int. J. Biosocial Med. Research</i> 11 (2) 163-180 (1989).	
	FY	Ewald, et al., "Hypomagnesemia in Diabetic Children" <i>Acta Padiatr Scand</i> 72:367-371 (1983)	
	FZ	Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, "Summary of the Second Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel 11)" <i>JAMA</i> 269 (23):3015-3023 (1993)	
	GA	Foot et al., "The Effects of Orthovanadate, Vanadyl and Peroxides of Vanadate on Glucose Metabolism in Skeletal Muscle Preparations in Vitro", <i>Molecular and Cellular Biochemistry</i> 109; 157-162 (1992).	
	GB	Franz et al., "Nutrition Principles for the Management of Diabetes and Related Complications" <i>Diabetes Care</i> 17 (5):490-518 (1994)	
	GC	Freund et al., "Chromium Deficiency During Total Parenteral Nutrition" <i>JAMA</i> 241 (5):496-498 (1979)	
	GD	Grant et al., "Chromium and Exercise Training: effect on obese women", <i>Medicine &amp; Science in Sports &amp; Exercise</i> , pp. 992-998 (1997).	
	GE	Gunnar et al., "Recommendations for Angioplasty after Intravenous Thrombolysis," <i>JAAC</i> , 16(2):249-292 (1990)	
	GF	Haffner et al., "Cardiovascular Risk Factors in Confirmed Prediabetic Individuals; Does the Clock for Heart Disease Start Ticking Before the Onset of Clinical Diabetes?" <i>JAMA</i> 263 (21):2893-2898 (1990)	
	GG	Haffner et al., "Insulin Resistance Implications for Type II Diabetes Mellitus and Coronary Heart Disease," <i>The American Journal of Medicine</i> , 103:152-162 August (1997)	
	GH	Haffner et al., "Prospective Analysis of the Insulin-Resistance Syndrome (Syndrome X)" <i>Diabetes</i> 41:715-722 (1992)	
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SK	GI	Halberstam et al., "Oral Vanadyl Sulfate Improves Insulin Sensitivity in NIDDM but Not in Obese Nondiabetic Subjects" <i>Diabetes</i> 45:659-666 (1996)	
	GJ	Hansson et al., "Effects of Intensive Blood-Pressure Lowering and Low-Dose Aspirin in Patients with Hypertension: Principal Results of the Hypertension Optimal Treatment (HOT) Randomised Trial, The lancet, 351:1755-1762 June (1998)	
	GK	Harris et al., "Onset of NIDDM Occurs at Least 4-7 Yr Before Clinical Diagnosis" <i>Diabetes Care</i> 15 (7):815-819 (1992)	
	GL	Hatwal et al., "Association of hypomagnesemia with diabetic retinopathy" <i>Acta Ophthalmologica</i> 67:714-716 (1989)	
	GM	Heath et al., "Platelet Adhesiveness and Aggregation in Relation to Diabetic Retinopathy" <i>Diabetologia</i> 7:308-315 (1971)	
	GN	Hennekens et al., "An Overview of The British and American Aspirin Studies" <i>The New England Journal of Medicine</i> 318 (14):923-924 (1988)	
	GO	Hermann et al., "Therapeutic Comparison of Metformin and Sulfonylurea, Alone and in Various Combinations" <i>Diabetes Care</i> 17 (10):1100-1109 (1994)	
	GP	Hirsh et al., "Aspirin and Other Platelet-Active Drugs; The Relationship Among Dose, Effectiveness, and Side Effects" <i>Chest</i> 108 (4):247S 257S (1995)	
	GQ	InterHealth Company., "Facts About Chromium Nutrition; Fact Sheet #1: The Importance of Niacin-Bound Chromium in Human Nutrition", (July 21, 1992).	
	GR	InterHealth Company., "Facts About Chromium Nutrition; Fact Sheet #2: Niacin-Bound Chromium Compounds Vary; ChromeMate's Oxygen- Coordinated Complex Found 18 Times More Potent", (October 5, 1992).	
	GS	InterHealth Company., "Facts About Chromium Nutrition; Fact Sheet #3 : UC Study finds ChromeMate More Bioavailable than Chromium Picolinate, Chromium Chloride" (October 14, 1992).	
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<b>APR 3 1 2001</b>		Applicant Stuart A. Fine et al.	
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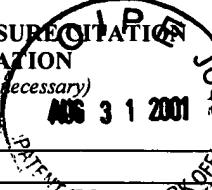
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**INFORMATION DISCLOSURE STATEMENT  
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AKT-053.02

Application Number

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Applicant

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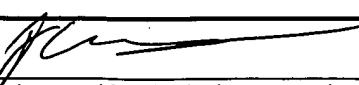
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages Etc.)

✓	KZ	Abraham et al., "The Effects of Chromium Supplementation on Serum Glucose and Lipids in Patients with and without Non-Insulin-Dependent Diabetes," Metabolism, 41(7):768-771 (1992)
	LA	Blondel et al., "In Vivo Insulin Resistance in Streptozotocin-Diabetic Rats - Evidence for Reversal Following Oral Vanadate Treatment," Diabetologia 32:185-190 (1989)
	LB	Colwell, John A., "DCCT Findings: Applicability and Implications for NIDDM," Diabetes Reviews, 2(3):277-291 (1994)
	LC	Cunningham, John J., "Micronutrients as Nutriceutical Interventions in Diabetes Mellitus," Journal of the American College of Nutrition, 17(1):7-10 (1998)
	LD	Dornan et al., "Double-Blind Evaluation of Efficacy and Tolerability of Metformin in NIDDM," Diabetes Care, 14(4):342-344 (1991)
	LE	Jovanovic-Peterson et al., "Chromium Supplementation for Gestational Diabetic Women (GDM) Improves Glucose Tolerance and Decreases Hyperinsulinemia," Diabetes, Abstract, 45(2) (1996)
✓	LF	Lardinois, Claude, "Type 2 Diabetes: Glycemic Targets and Oral Therapies for Older Patients," Geriatrics, 53(11):22-39 (1998)
		<del>Role List 1998, Items 12-005 and 12-054; Introduced by the Examiner Copies are Annexed</del>
EXAMINER		DATE CONSIDERED 5/30/03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.